Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13229

0 - FRONT

CFSAN

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN

 CFSAN

Form Approved- OMB No 0910-0291 Expires 12/31/96
See OMB statement on reverse

FDA use only
Triage unit sequence # 93608 / 3229

A. Patient information

1. Patient Identifier	2. Age at time of event: 15 or Date of birth:	3. Sex	4. Weight
[redacted] In confidence		☒ female ☐ male	125 lbs or ____ kgs

B. Adverse event or product problem

1 ☒ Adverse event and/or ☐ Product problem (e g , defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

- ☐ death ____ (mo/day/yr)
- ☒ life-threatening
- ☒ hospitalization 2 days
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other ____

3 Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
not reported	12/2/98

5 Describe event or problem

Patient took 6 x 10mg capsules of Metabolift (contains 10mg ephedra/capsule) at once (directions for use : 2 capsules three times a day). She was admitted to the ER for complaints of chest pain. Upon arrival had prolonged QT interval. Lasted 24 hours and then normalized; chest pain disappeared within 24 hours - had normal tread mill test, normal QT interval that shortened with exercise

6 Relevant tests/laboratory data, including dates

multiple 12 lead EKGs

RECD. DEC 0 2 1998 MEDWATCH CTU

7 Other relevant history, including preexisting medical conditions (e g , allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

White female smoker with no other medical conditions, known drug use or allergies

CTU 93608

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)

#1 Metabolift (Mfg=TwinLab)

#2

2 Dose, frequency & route used	3 Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 6 x 10mg capsules	#1 6 weeks
#2	#2

4 Diagnosis for use (indication)	5 Event abated after use stopped or dose reduced
#1 self dx for weight loss	#1 ☒ yes ☐ no ☐ doesn't apply
#2	#2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)	7 Exp. date (if known)	8 Event reappeared after reintroduction
#1 unk	#1 unk	#1 ☐ yes ☐ no ☒ doesn't apply
#2	#2	#2 ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only) – –

10 Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1 Brand name

2 Type of Device

3 Manufacturer name & address

RECEIVED DEC 9 1998

4 Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other

5 Expiration Date (mo/day/yr)

6
model #
catalog #
serial #
lot #
other #

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1 Name & Address phone # [redacted]

[redacted]

2 Health professional?	3 Occupation	4 Also reported to
☒ yes ☐ no	ped. nurse pract.	☐ manufacturer ☐ user facility ☐ distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (1/96) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

Taken By Telephone

000001

UNITED STATES FOOD AND DRUG ADMINISTRATION

CONSUMER COMPLAINT/INJURY REPORT

1 COMPLAINT NUMBER: SEA 6385 GPSAN

2. DATE OF COMPLAINT: 12/22/98 13229

3. FORM OF COMPLAINT
(1) ☐ TELEPHONE (4) ☒ OTHER
(2) ☐ LETTER
(3) ☐ VISIT

4. SOURCE OF COMPLAINT
☐ CONSUMER ☐ TRADE SOURCE
☒ GOVERNMENT ☐ OTHER
☐ LOCAL ☐ STATE ☒ FEDERAL

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS: [redacted] (sent to SEA-DO by CFSAN)
b TELEPHONE NUMBER
HOME.
WORK: [redacted] pager

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT/INJURY
Fifteen y/o female patient took six 10 mg. capsules of product at once (directions for use: 2 capsules three times a day). She was admitted to the ER for complaints of chest pain.

b DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? ☐ NO ☐ YES *(If Yes, explain in Remarks)*

7. INJURY OR ILLNESS RESULTED
(1) ☐ NO
(2) ☒ YES
(If "yes" complete items a through d)

a. DEIO/EMOPS *(HFC-130)* NOTIFIED
(1) ☐ NO
(2) ☒ YES
DATE 12/22/98 (faxed)

b TYPE SYMPTOM ONSET (HR)
(1) ☐ VOMITING
(2) ☒ NAUSEA
(3) ☐ DIARRHEA
(4) ☐ FEVER
(5) ☐ SKIN/EYE IRR
(6) ☐ HEADACHE
(7) ☒ OTHER
chest pain

c. ATTENDING HEALTH PROFESSIONAL
(1) ☐ NO (2) ☒ YES
(If "yes, give name, address, phone)

d HOSPITALIZATION REQUIRED
(1) ☐ NO (2) ☒ YES
(If "yes", give name, address, phone, date)
[redacted]

8. PRODUCT AND LABELING
a. BRAND NAME: Metabolift
b. PRODUCT NAME:
c SIZE AND PACKAGE TYPE: capsules
d. NAME AND LOCATION OF STORE WHERE PURCHASED:
e. LOT/SERIAL NUMBER:
EXP/USE BY DATE:
f DATE PURCHASED:
g PRODUCT USED (1) ☐ NO (2) ☒ YES
DATE:
h AMT REMAINING:

9. MANUFACTURER/ DISTIBUTOR OF PRODUCT
a. HOME DISTRICT: NYK
b. CFN: 2195141
c. NAME AND LOCATION OF FIRM:
Twin Laboratories
150 Motor Parkway
Hauppauge, NY 11788
d IMPORT PRODUCT
(1) ☒ NO
(2) ☐ YES

10. EVAULATION AND DISPOSITION
a. PROBLEM KEYWORD
(1) CODE: RX (2) DESCRIPTION: chest pain
b. EVALUATION
(1) ☐ NOT AN FDA OBLIGATION
(2) ☐ OBLIGATION, NO VIOLATION
(3) ☒ FDA ACTION INDICATED
(4) ☐ INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c. DISPOSITION
(1) ☒ IMMEDIATE FOLLOW-UP
(2) ☐ F/U NEXT EI
(3) ☐ CLOSED WITHOUT FURTHER INVESTIGATION
(4) ☐ REFERRED TO OTHER FEDERAL AGENCY
(5) ☐ REFERRED TO STATE/ LOCAL AGENCY
(6) ☐ REFERRED TO OTHER FDA DISTRICT
(7) ☐ REFERRED TO OCI

11. PRODUCT CODE: 54FDE09

12 INFORMATION COPIES TO
☐ HFC-130 ☐ HFD-730
☐ HFM-650 ☒ HFS-635
☐ HFV-210 ☐ HFZ-530
☒ OTHER Orig. sent to HFS-636 2/10/99 Jdc

REMARKS
(copy to NYK)
Read 2/11/99 DOEP

99 FEB 12 A11:07

NAME AND TITLE: Janice D. Carter, CCC
DATE: 12/22/1998

FORM FDA 2516 (5/11/98)

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN NES-635

000002

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER SEA 6385 CFAN #13229

2.a. ACTION REQUESTED
(1) ☐ INVESTIGATION
(2) ☒ COLLECT SAMPLE
(3) ☐ INSPECTION
(4) ☒ OTHER:

2.b. REMARKS (Additional details)
Investigate per IOM 901. Per CFSAN's request: Collect medical records; complete Adverse Event Questionnaire (attached). Collect consumer's sample and labeling. Send sample to SEA-DO Lab for analysis.

2.c. REQUESTING OFFICIAL'S NAME AND TITLE
Janice D. Carter, CCC

2.d. DATE REQUESTED ~~12/22/98~~ 12/28/98

2.e. PRODUCT NAME Metabolift

3.a. ASSIGNED TO:

3.b. DUE BY:

4.a. ACTION TAKEN
(1) ☒ INVESTIGATION
(2) ☐ SAMPLE COLLECTED
(3) ☐ INSPECTION
(4) ☐ NONE

4.b. SAMPLE NUMBER(s) N/A

4.c. DESCRIPTION OF ACTION TAKEN
ASSIGN RECD 12-28-98. UNABLE TO REACH COMPLAINANT (also Health Pro) [redacted] (aka [redacted]) UNTIL 12/30. PER [redacted] - PATIENT DIFFICULT TO REACH. SHE TRIED TO REACH PATIENT BY TELEPHONE (PAGER) UNTIL 1-11-99. THEN SENT LETTER W/ RECORDS RELEASE FORM. MESSAGE FROM [redacted] ON 1-26-99: FORM REC'D & WILL WALK TO MED. RECORDS. CALL FROM MED. RECORDS ON 2-2-99 - RECORDS READY. P/U ON 2-3-99. MED RECORDS SHOW INITIAL TREATMENT AT [redacted] DUE [redacted] (FIRST KNOWLEDGE OF THIS). REFERRED TO [redacted] DUE TO LONG QT (500 msec.) PATIENT HAS COMPLETE RECOVERY I WAS UNABLE TO MAKE ARRANGEMENTS TO INTERVIEW PATIENT. PRODUCT INFO MFR FROM INTERNET (www.twinlab.com). SINCE REACTION DUE TO OVERDOSE EPHEDRA/CAFFEINE, NO F/U PLANNED AT [redacted] UNLESS SPECIFICALLY REQUESTED.

4.d. ACTION OFFICIAL'S NAME AND TITLE ALAN GRUPE - INVESTIGATOR

4.e. ACTION DISTRICT SEA

4.f. DATE COMPLETED 2-3-99

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

5.a. HOME DIST. NY

5.b. ~~CF NO.~~ EEI 3002195141

5.c. NAME AND ADDRESS TWIN LABORATORIES 150 MOTOR PARKWAY HAUPPAUGE, NY 11788

6. PROGRAM DATA

6.a. OPERATION 13

6.b. PAC 03R801

6.c. PRODUCT CODE 54EDE09

6.d EMP. HOME DIST. SEA

6.e. EMP. NO. 089

6.f. POS CL. 2

6.g. HOURS 18

7. EVALUATION
(0) ☐ PENDING
(1) ☒ NO ACTION INDICATED (NAI)
(2) ☐ VOLUNTARY ACTION INDICATED (VAI)
(3) ☐ OFFICIAL ACTION INDICATED (OAI)
(4) ☐ NOT AN FDA OBLIGATION
(5) ☐ REFERRED TO HOME DISTRICT
(6) ☐ INSUFFICIENT INFO. UNABLE TO EVAL.
(7) ☐ REFERRED TO OCI

8. FINAL DISPOSITION
(1) ☐ FOLLOW-UP NEXT E1
(2) ☐ WARNING LETTER
(3) ☐ CITATION
(4) ☐ SEIZURE
(5) ☐ INJUNCTION / PROSECUTION
(6) ☐ REFERRED TO OTHER AGENCY
(Indicate Agency in **Remarks***)*
(7) ☐ RECALL
(8) ☒ NO ACTION

9. INFO. COPIES TO:
☐ HFB-100
☐ HFD-730
☐ HFV-236
☐ HFZ-343
☐ HFC-161
☐ HFS-635
☒ ~~HFS-630~~
☐ _____
☐ _____
☐ _____
☐ _____
☐ _____
☐ _____

REMARKS

NAME AND TITLE OF DISPOSITION OFFICIAL AAWilliams, PM

DISPOSITION Seq

DISPOSITION DATE 02/09/99

Adverse Event Questionnaire

Complaint Number: SEA 6385
CFSAN #13229

Investigator: ALANGRUE

Consumer Information

Date of Report: 02/03/99 (MM/DD/YY)

Initial Report Source: ☐ORA Consumer Injury
☐Telephone ☐Correspondence ☒MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted]

Gender: ☒F ☐M

Age: 15

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 11-21-98
Previous Adverse Effects to Product Type: ☐Yes ☐No

Give the site of consumption/ingestion (e.g. home, restaurant, office): HOME ?

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
NAUSEA + CHEST PAINS - ONSET UNKNOWN

How long did the symptoms last?
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). TOOK 6 CAPSULES w/ 2 double lattes

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
Metabolift only one known
Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☒Unknown ☐Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☒Unknown ☐Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☒Nurse ☐Pharmacist
☐Other (specify) NURSE PRACTITIONER

What medical tests were performed and what were the results?
EKG - see medical records -
What was the medical diagnosis? OVERDOSE
What treatment(s) was given (e.g., drugs, other)?
NONE

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☒Yes ☒No → depression

SEA 6385

Product Category

CFSAN #13229

1. Adverse event attributed to:
   - ☐ **Medical Food** (under medical supervision) ☐ **Infant Formula**
   - ☒ **Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   - ☐ **Other** (traditional food) _____

Other Product Problems

2. ☐ Foreign Object
(specify): _____

3. ☐ Other (specify):
_____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

TWINLABORATORIES
150 MOTOR PARKWAY
HAUPPAUGE NY 11788

2 capsules B4 each meal NOT to EXCEED 6/day.
Metabol. ft

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

☐ Check here if ingredients are unknown

MA-HUANG EXTRACT 334 mg. (6% Ephedra)

GUARANA EXTRACT 910 mg. (22% caffeine)

Chromium 200 mcg.

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

- ☐ Aspartame
- ☐ Monosodium Glutamate
- ☐ Sulfite
- ☒ Other EPHEDRA + CAFFEINE
- ☐ Unknown

☐ Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐ Yes ☒ No ☐ Unknown

Product Sample Available: ☐ Yes ☒ No ☐ Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐ Yes ☒ No

Life-Threatening: ☒ Yes ☐ No

Hospitalization: ☒ Yes ☐ No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☐ Yes ☒ No

Did the adverse event result in a congenital anomaly: ☐ Yes ☒ No